

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 FEB 2005

WIPO PCT

Applicant's or agent's file reference 12432280	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/AU2004/000407	International filing date (day/month/year) 31 March 2004	Priority date (day/month/year) 31 March 2003	
International Patent Classification (IPC) or national classification and IPC Int. Cl.⁷ G01N 35/00			
Applicant VISION BIOSYSTEMS LIMITED et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 23 December 2004	Date of completion of the report 18 February 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer RAJEEV DESHMUKH Telephone No. (02) 6283 2145

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International application No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1 (b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
 - ☐ the international application as originally filed/furnished
 - ☐ the description:
 - pages as originally filed/furnished
 - pages* received by this Authority on with the letter of
 - pages* received by this Authority on with the letter of
 - ☐ the claims:
 - pages as originally filed/furnished
 - pages* as amended (together with any statement) under Article 19
 - pages* received by this Authority on with the letter of
 - pages* received by this Authority on with the letter of
 - ☐ the drawings:
 - pages as originally filed/furnished
 - pages* received by this Authority on with the letter of
 - pages* received by this Authority on with the letter of
 - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)):
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: 14

because:

☐ the said international application, or the said claims Nos.

relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV

Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:
Please see the Supplemental Sheet.

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-13

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box IV

The international application does not comply with the requirements of unity of invention because it does not relate to an invention or to a group of inventions so linked as to form a general inventive concept. In coming to this conclusion, the International Searching Authority has found that there are three inventions:

Claim 1: A method of preparing a blended reagent in an automated biological reaction apparatus including: ascertaining a blended reagent is required, preparing the blended reagent before its application is required. It is considered that "ascertaining a blended reagent is required, preparing the blended reagent before its application is required" comprises a first "special technical feature".

Claim 8: A method scheduling application of reagent to a number of slides in an automated biological reaction apparatus including: grouping at least one group of slides together as a batch, ascertaining whether a blended reagent is to be applied to any slide within the batch, and scheduling the step of preparing the blended reagent before the step of applying the blended reagent to the slide. It is considered that "grouping at least one group of slides together as a batch, ascertaining whether a blended reagent is to be applied to any slide within the batch, and scheduling the step of preparing the blended reagent before the step of applying the blended reagent to the slide".

Claim 13: An automated biological reaction apparatus having a mixing vessel, reagent containers, a robotic arm having a dispenser for dispensing fluid from reagent containers to slides or mixing vials, a mixing vial and a controlling computer. It is considered that "a mixing vessel, reagent containers, a robotic arm having a dispenser for dispensing fluid from reagent containers to slides or mixing vials, a mixing vial and a controlling computer" comprises a third "special technical feature".

Claim 14: A mixing vial having a mount, a plurality of mixing chambers, and an identification means. It is considered that "a mixing vial having a mount, a plurality of mixing chambers, and an identification means" comprises a fourth "special technical feature".

Since the abovementioned groups of claims do not share any of the special technical features identified, a "technical relationship" among the inventions—as defined in PCT Rule 13.2—does not exist. Accordingly the international application does not relate to a single invention or to a single general inventive concept. It was however considered that the first and the second inventions could be searched together with little additional effort, no additional fee is being requested for the second invention.

As the search for the third and the fourth invention would have required more than a little additional search effort over that for the first and the second invention, additional search fees were warranted.

In response to the invitation to pay additional fees, the applicant paid an additional search fee in respect of claim 13. Consequently claim 14 was not subjected to an international search and therefore no international search report—and no written opinion of the international searching authority—has been established in respect of claim 14.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	YES
	Claims 1-13	NO
Inventive step (IS)	Claims	YES
	Claims 1-13	NO
Industrial applicability (IA)	Claims 1-13	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

US 2002/0090730 A1 (ECKERT et al.) 11 July 2002.
 US 2002/0072122 A1 (COPELAND et al.) 13 June 2002.
 US 6349264 B1 (RHETT et al.) 19 February 2002.
 US 5609822 A (CAREY et al.) 11 March 1997.
 EP 485816 A2 (GRUPO GRIFOLS S.A.) 20 May 1992.
 US 4678752 A (THORNE et al.) 7 July 1987.
 WO 2001/051909 A1 (LAB VISION CORPORATION) 19 July 2001.

NOVELTY (N), INVENTIVE STEP (IS) CLAIMS 1-13

THORNE discloses that the transfer of liquids from reservoir 78 into the different receptacles facilitates the mixing of the sample liquid and any liquid reagents originally included in one or more receptacles of the reagent package to thereby form one or more reaction mixtures for subsequent analysis. In light of THORNE the claimed invention does not appear to be novel or to involve an inventive step.

The remaining documents do not disclose the step of blending reagents in an automated biological reaction apparatus. These documents disclose that the reagents are supplied either from the bulk containers or from reagent packs containing pre-packaged reagents. However if a particular reaction needs a blended reagent, a person skilled in the art would find it obvious to provide for the mixing step—and this would not involve overcoming any technical difficulties or require inventive ingenuity, as the step of preparing the blended reagent before it is required is technically trivial. Consequently claims 1-13 do not appear to involve an inventive step in light of any of the cited documents, or alternatively in light of the obvious combination of any of the cited documents with THORNE.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO 2004/001390 A1	31 December 2003	20 June 2003	20 June 2002

WO 2004/001390 A1 (VISION BIOSYSTEMS LIMITED) 31 December 2003. This application is related to the present application because the priority document for the present application (AU 2003901871) is one of the two priority documents for WO 2004/001390. However WO 2004/001390 also claims priority from AU PS3114 which has an earlier priority date. Page 15, line 18–page 16, line 24 describe essentially what is claimed in present claims 1–13. The priority claim of WO 2004/001390 in relation to AU PS3114 in relation to this disclosure has not been verified.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosureDate of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The applicant is invited to insert into the specification references to the prior art cited in the international search report and to discuss the invention in relation to the prior art so as to put the invention into proper perspective.
2. The independent claims have been drafted in such a manner that it is not clear what inventive contribution these claims make over the prior art. The two-part claim format in the PCT Rules may be more appropriate.
3. The claims are not clear. For example claim 13 lists a number of technical features but does not define any interrelationship between these features. Claim 1 has the method step of "preparing the blended reagent before its application is required"—this appears to be stating the obvious. Certainly it would be of no use preparing the blended reagent *after* its application was required.